Summary of Safety and Effectiveness K102435

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Trade Name:	BeyondImage Workstation
Version Number:	2.0
Common Name:	Picture Archiving and Communication System (PACS)
CFR Section:	21 CFR Part 892.2050
Classification Name:	Picture Archiving and Communication System (PACS).
Product Code:	LLZ
Device Class:	Class II
Manufacturer and Distributor:	Neusoft Medical Systems Co., Ltd. No.16, Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China Post Code : 110179
Submitter:	Contact : Tian Yuehui Title : Manager of Quality Management Department Tel : 86-24-83660646 Fax : 86-24-83660563 E-Mail : Tianyh@neusoft.com Summary prepared :Aug. 13, 2010

Safety and Effectiveness Information

Intended Uses:

BeyondImage Workstation is a software application that is used for viewing medical images. BeyondImage Workstation receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and digital radiographic devices). Images are stored, communicated, processed and displayed on the local disc of a workstation and/or across computer networks at distributed locations. Taking that users may perform when viewing images include, but are not limited to adjustment of window width and center; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images, it also provides standard Multi-Planar Reconstruction (MPR) views,Curved-Planar Reconstruction (CPR) views and 3D views of Volume Rendering for digital images from CT, MR, and PET unit. In addition, using BeyondImage Workstation, users can edit and print report.

BeyondImage Workstation cannot display and process mammograms.

Typical users of BeyondImage Workstation are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Device Description:

BeyondImage Workstation is a software application that provides image viewing and manipulation in a diagnostic imaging setting. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM format. BeyondImage Workstation can also transfer images in DICOM 3.0 format over a medical imaging network, as well as exporting images to applications in other proprietary formats.

Predicate Device:

K092235 : BeyondImage Workstation 1.0
K060505 : Barco Voxar 3D 6.1

Statement of Substantial Equivalence:

The BeyondImage Workstation 2.0is comparable and substantially equivalent to the BeyondImage Workstation 1.0(K092235) and the Barco Voxar 3D 6.1 (K060505).

BeyondImage Workstation 2.0, BeyondImage Workstation 1.0and Barco Voxar 3D 6.1 are all available as "software only" application that run under Microsoft Windows operating systems on readily available computer hardware. All applications include image and report viewing and a set of imaging measurements and manipulation tools. All three are DICOM compliant systems capable of receiving and storing images and moving imaging studies using DICOM Query/Retrieve.

The BeyondImage Workstation 2.0 and the BeyondImage Workstation 1.0 share similar technological specifications. Both of them support DICOM protocol for communication of images with other medical imaging devices, and they both provide the functions such as adjustment of window width and center; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images etc. Furthermore, they both provide standard Multi-Planar Reformation (MPR) views and 3D views of Volume Rendering.

The BeyondImage Workstation 2.0has the similar technological characteristics with the Barco Voxar 3D 6.1. Both of them support DICOM protocol for communication of images with other medical imaging devices, and they both provide the functions such as adjustment of window width and center, scout line, annotation and measurement of regions of interest; and inversion, rotation, and flips of images etc. Furthermore, they both provide function ofCurved-Planar Recontruction(CPR)..

According to the comparison based on the requirements of 21.CFR 807.87, we state that these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Tian Yuehui
Manager of Q&R Department
Neusoft Medical Systems, Co., Ltd.
No 16, Shiji Road, Hunnan Industrial Area
Shenyang, Liaoning, 110179
CHINA

OCT 15 2010

Re: K102435
Trade/Device Name: BeyondImage Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 16, 2010
Received: August 26, 2010

Dear Mr. Yuehui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

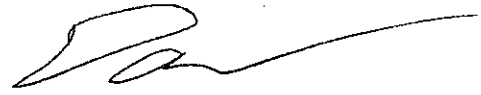
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

OCT 15 2010

510(k) Number: K102435

Device Name: BeyondImage Workstation

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Prescription Use YES (Part 21 CFR 801 Subpart D)

Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102435